

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/645,415	BERMUDES ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ram R. Shukla	1632	

**-- Th MAILING DATE of this communication app ars on the cover she t with th correspond nc address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/13/04.
2. ☒ The allowed claim(s) is/are 258-266.
3. ☒ The drawings filed on 24 August 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachm nt(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance              |
|   | 9. <input type="checkbox"/> Other _____.   |

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. Authorization for this examiner's amendment was given in a telephone interview with Albert Wai-Kit Chan on 01/05/2005.

2. The application has been amended as follows:

#### IN THE SPECIFICATION:

Pages labeled "i – vi" have been deleted.

#### IN THE CLAIMS:

Claims 2, 5-14, 16, 26, 29-38, 40, 49, 52-61, 63, 100-257 have been cancelled.

Following new claims 258-266 have been added. It is noted that new claims 258-266 are the only currently pending and allowed claims. Any other claims have been cancelled.

- 258. An attenuated tumor-targeted bacteria comprising a first nucleic acid molecule encoding a primary effector molecule operably linked to a eukaryotic promoter and a second nucleic acid molecule encoding a secondary effector molecule operably linked to a eukaryotic promoter, wherein said attenuated tumor-targeted bacteria is *Salmonella*, said primary effector molecule is endostatin, and said secondary effector molecules is bacteriocin release factor (BRP).
- 259. The attenuated tumor-targeted bacteria of claim 258, wherein the BRP is obtained from the cloacin DF13 plasmid.
- 260. The attenuated tumor-targeted bacteria of claim 258, wherein the *Salmonella* is an msbB *Salmonella* mutant.
- 261. A pharmaceutical composition comprising a pharmaceutically acceptable carrier and an attenuated tumor-targeted bacteria comprising a first nucleic acid molecule encoding a primary effector molecule operably linked to a eukaryotic promoter and a second nucleic

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acid molecule encoding a secondary effector molecule operably linked to a eukaryotic promoter, wherein said attenuated tumor-targeted bacteria is *Salmonella*, said primary effector molecule is endostatin, and said secondary effector molecule is bacteriocin release factor (BRP).

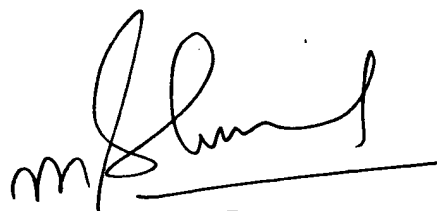
- 262. The pharmaceutical composition of claim 261, wherein the BRP is obtained from the cloacin DF13 plasmid.
- 263. The pharmaceutical composition of claim 261, wherein the *Salmonella* is an msbB *Salmonella* mutant.
- 264. A method for delivering a primary effector molecule to a subject to treat a solid tumor cancer, comprising administering to said subject a pharmaceutical composition comprising a pharmaceutically acceptable carrier and an attenuated tumor-targeted bacteria comprising a first nucleic acid molecule encoding a primary effector molecule operably linked to a eukaryotic promoter and a second nucleic acid molecule encoding a secondary effector molecule operably linked to a eukaryotic promoter, wherein said attenuated tumor-targeted bacteria is *Salmonella*, said primary effector molecules is endostatin, and said secondary effector molecule is bacteriocin release factor (BRP).
- 265. The method of claim 264, wherein the BRP is obtained from the cloacin DF13 plasmid.
- 266. The method of claim 264, wherein the *Salmonella* is an msbB *Salmonella* mutant. --

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (571) 272-0735. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for TC 1600 is (571) 273-8300. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (571) 272-0532.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ram R. Shukla, Ph.D.  
Primary Examiner  
Art Unit 1632



RAM R. SHUKLA, PH.D.  
PRIMARY EXAMINER